REMARKS

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (Claims 1 and 12) drawn to proteins of SEQ ID NO:1-37 and pharmaceutical compositions thereof;

Group II (Claims 2-11) drawn to polynucleotides comprising SEQ ID NO:38-74, complementary sequences, microarrays, vectors, host cells and recombinant methods of expression thereof;

Group III (Claims 13-15) drawn to antibodies which binds to the proteins of Group I, agonists and antagonists of the proteins of Group I;

Group IV (Claims 16 and 17) drawn to methods of stimulating cell proliferation and methods of treating cancer comprising administering a protein of Group I;

Group V (Claims 18 and 19) drawn to methods of treating cancer and methods of treating an immune response comprising administering antagonists to the protein of Group I; and

Group VI (Claims 20-22) drawn to methods for detecting a polynucleotide of Group II and methods for the simultaneous detection of the polynucleotides of Group II comprising polynucleotide amplification and hybridization.

Claims 1-22 have been canceled. Claims 23-42 have been added. Therefore, Claims 23-42 are pending. New Claims 23 and 24 correspond to the original claims of Group I (Claims 1 and 12, now canceled). New Claims 25-33, 39, and 41-42 correspond to the original claims of Group II (Claims 2-11, now canceled). New Claims 34, 35, 36, and 40 correspond to the original claims of Group VI, (Claims 20-22, now canceled).

Applicants hereby elect to prosecute newly added Claims 25-33, 39, and 41-42, which correspond to the original claims of Group II (Claim 2-11, now canceled), with traverse. Applicants also traverse the "restriction requirement" to elect a particular SEQ ID NO:. Applicants provisionally elect the portion of Claims 25-33, 39, and 41-42 directed to SEQ ID NO:37 (polypeptide) and SEQ ID NO:74 (polynucleotide), also with traverse.

Applicants first submit that the invention encompassed by the claims of Groups I (Claims 23 and 24, drawn to polypeptides) could be examined at the same time as the invention encompassed by the claims of Groups II without undue burden on the Examiner. For example, a search of the prior art to determine the novelty of the polynucleotides of Groups II would provide information regarding the novelty of the polypeptides of Groups I.

Applicants second submit that Claims 34, 35, 36, and 40 (Group VI), as well as newly added Claims 37 and 38, are method of use claims which should be examined together with the polynucleotides of Group II, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Accordingly, because the search required to identify prior art relevant to the claims of Groups I, II, and VI, as well as newly added Claims 37 and 38, would substantially overlap, Applicants respectfully submit that examination of Claims 23-42 would pose no undue burden. Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of Claims 23-42.

Applicants also traverse this restriction requirement insofar as it is, in effect, a requirement for election of species as between elements in Markush groups (those elements being, respectively, SEQ ID NO:1-37 with respect to the polypeptides, and SEQ ID NO:38-74 with respect to the polynucleotides). The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 8th edition of the M.P.E.P. (August 2001) at § 803.02 regarding restriction requirements in Markush-type claims:

> PRACTICE RE MARKUSH-TYPE CLAIMS
>
> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.**

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *non-elected species,* the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the

> rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, the present Restriction Requirement does not meet the Patent Office's own requirements.

First, **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. The polynucleotides of the present invention, as well as the polypeptides they encode, share a common utility in, for example, toxicology studies based on expression profiling.

Second, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," the M.P.E.P states that "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. § 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits." This clearly applies in the present case.

Finally, the Examiner's attention is directed to the M.P.E.P. at § 803.04 (Restriction - Nucleotide Sequences, EXAMPLES OF NUCLEOTIDE SEQUENCE CLAIMS) which states:

> Applications claiming more than ten individual independent and distinct nucleotide sequences in alternative form, such as set forth in example (A), will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.
>
> Applications claiming only a combination of nucleotide sequences, such as set forth in example (B), will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide

sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

The instant application claims thirty-seven polynucleotide sequences, and the claims examined clearly should not be limited by an election of only a single sequence under the guidelines set forth in the M.P.E.P. at § 803.04.

Therefore, it is respectfully submitted that, upon searching and examining SEQ ID NO:37 (polypeptide) and SEQ ID NO:74 (polynucleotide) and finding no prior art over which SEQ ID NO:37 and SEQ ID NO:74 can be rejected, the Examiner must extend the search of the Markush-type claim to include at least nine additional non-elected polypeptide species chosen among SEQ ID NO:1-36 and at least nine additional non-elected polynucleotide species chosen among SEQ ID NO:38-73.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

Please charge Deposit Account No. **09-0108** in the amount of **$110.00** as set forth in the enclosed fee transmittal letter. If the USPTO determines that an additional fee is necessary, please charge any required fee to Deposit Account No. **09-0108.**

Respectfully submitted,

INCYTE GENOMICS, INC.

Date: May 28, 2002

Susan K. Sather

Susan K. Sather
Reg. No. 44,316
Direct Dial Telephone: (650) 845-4646

3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-22 have been canceled.

Claim 23-42 been added.